

Appln. No. 10/019,400
Amdt. dated October 14, 2003
Reply to Office Action of June 25, 2003

REMARKS

Applicants respectfully request the Examiner to enter this Amendment, reconsider their application, and issue an allowance.

Applicants' counsel acknowledges the August 5, 2003 telephone discussion with the Examiner. It was pointed out the Office Action asserted reliance on specific teachings in the cited reference(s) but such teachings were not in the English language Abstract of record. The Examiner acknowledged the PTO was relying on a translation of JP-A-04-189779. The undersigned pointed out that such translation was not previously disclosed to Applicants, nor copy furnished with the June 25, 2003 Office Action. The Examiner provided a copy of the translation by facsimile to the undersigned on August 5, 2003, which is more than a month after the Office Action was mailed by the PTO. The Examiner did not re-set the response date despite MPEP 710.06 and thus the PTO is deemed responsible under the AIPA for any slight delays in prosecution.

Claims 2-4 remain unamended, whereas claim 1 has been edited, and claim 5 has been amended to avoid improper multiple dependent claim format. Amended claim 1 simply reflects improved colloquial English and deletion of the unnecessary expressions "characterized by" and "and by", which improvements in idiomatic English have no affect whatsoever on claim scope. New claim 6 corresponds to claim 5, but depends on only claim 4, new claims 7 et seq. find support throughout the specification, including the Examples.

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Claims 1-4 define unobvious inventions over JP-A-04-189779 ("Yuichi").

An embodiment of the claimed invention comprises a patch package including a laminated package material with a saturation hygroscopicity of 2-30 g/m² under atmosphere conditions with a temperature of 25°C and a relative humidity of 75%, wherein a hygroscopic material layer composed of a first resin containing 20-40 wt% of an inorganic filler is situated between a moisture-permeable material layer composed of a second resin and having a moisture permeability of 40-120 g/m²/day and a screen material layer which blocks penetration of moisture and light, and by being shaped into a pouch with the moisture-permeable material layer on the inside.

When the moisture permeability of the moisture-permeable material layer and the inorganic filler content of the hygroscopic material layer are within the aforementioned ranges, the saturation hygroscopicity of the laminated packaging material is kept within 2-30 g/m² under atmosphere conditions with a temperature of 25°C and a relative humidity of 75%. If the saturation hygroscopicity of the laminated packaging material is less than 2 g/m², the moisture present in the interior space of the patch package may not be sufficiently absorbed into the laminated packaging material, and therefore when a patch is accommodated in the patch package, the drug in the patch may then easily separate out.

On the other hand, if the saturation hygroscopicity of the laminated packaging material is greater than 30 g/m², the moisture present in the interior space may be absorbed into the laminated packaging material to an extent creating an unsuitably dry state in the patch. When a patch is accommodated therein, this will lead to evaporation of the adhesive component and volatile components in the patch, tending to lower the

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adhesive strength. The patch package of the invention therefore satisfactorily maintains the humidity in the interior space within a range suitable for a patch. Thus, when a patch is accommodated in the patch package, it is possible to adequately prevent separation of the drug in the patch without risking impairment of the adhesive strength of the patch.

Contrary to the Office Action, “[t]he package of Yuichi does [not] expressly disclose the specific properties at permeabilities claimed by the Applicant.” Office Action, page 3.

The Yuichi reference - the Abstract or the PTO translation - nowhere “expressly disclose[s] the specific material properties and permeabilities claimed by the Applicant.”

Applicants request an Examiner’s affidavit since the cited reference does not contain the teachings alleged in the Office Action.¹

The reference to one-sentence in the PTO translation at page 6, about thickness and material of the adhesive layer 14 does not constitute the “expressly disclose” as alleged in the Office Action, nor teach the permeability of the moisture-permeable layer or even the saturation hygroscopicity of the packaging material. The one-sentence passage doesn’t disclose, nor would it have suggested the results reported in the present specification for the present claimed invention.

¹ See, In re Lee, 277 F.3d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); In re Zurko, 258 F.3d 1379, 1386, 59 USPQ, 2d 1693, 1897 (Fed. Cir. 2000). Rote reliance on either the Boesch or Aller decisions in the Office Action is no substitute for teachings absent from the applied art.

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Thus, at the outset, this rejection appears to be at most, an obvious to try situation, which is not a basis for a sustainable rejection.

Claim 2 would have been unobvious over the Yuichi reference. The reference does not disclose nor would it have suggested a moisture permeable layer of a second resin comprised of LDPE and having a moisture permeability of 40 - 120 g/m²/day. The reference does not disclose nor would it have suggested a screen layer as claimed.

Claim 3 would have been unobvious to a person of ordinary skill in the art. The June 25, 2003 Office Action asserts the Yuichi reference teaches "a thickness of 10-50 μm ." The August 5, 2003 facsimile from the Examiner referred to a PTO translation of Yuichi at page 5. However, when actually read, the cited passage at page 5 relates to the Yuichi substrate 12 "set at approximately 10-50 μm ." The Yuichi substrate 12 "is made of material ..., e.g., aluminum composite film." (PTO translation, page 5.) This does not at all support the Office Action at page 4, lines 3-5. The Yuichi substrate 12 can be 10-50 μ . The Yuichi water-absorbing layer 13 is apparently not characterized by a numerical value for thickness in the PTO translation at pages 5-6. However, if the Examiner's reasoning were applied, the Yuichi water-absorbing layer 13 could be as thick as 150 μ , especially since in Figure 1, the layer 13 is at least about 3x the thickness of layer 12. The reference does not, in fact, appear to describe the thickness of the package as alleged in the Office Action.

Claim 4 depends from anyone of claims 1, 2 or 3. Claim 4 would have been unobvious to a person of ordinary skill in the art. Yuichi does not disclose the heat seal strength in claim 4. Yuichi does not disclose the thickness in claim 3. Yuichi does not disclose the resins or screen material layer of claim 2. Yuichi does not disclose the

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permeability and other parameters in claim 1. This reference lacks the disclosure which would have suggested the claim 4 invention to a person of ordinary skill in the art.

Having addressed all matters, Applicants respectfully solicit a Notice of Allowance.

Respectfully submitted,

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